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09/869,540	06/27/2001	Masaaki Mori	56001(46342)	4354

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EDWARDS & ANGELL, LLP
P.O. BOX 9169
BOSTON, MA 02209

EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/869,540

Applicant(s)

MORI ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's amendment and election of Group I invention, claims 1, 2 and 8-12 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Following the amendment, claims 3-7 are canceled.

Currently, claims 1, 2 and 8-12 are pending and under consideration.

Formal Matters:

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to *a single paragraph* on a separate sheet within the range of 50 to 150 words. It is important that the abstract *not exceed 150 words* in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Appropriate correction or a new abstract is required.

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Claims

Claims 8-10 are objected to as each is drawn to two inventions, a method and a kit. Separate claims should be used for the method, and for the kit.

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Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements. See MPEP § 2172.01. The omitted elements are: the method steps. The term "using ..." is not a step. The claim is further indefinite for the recitation of "its derivative" as it is unclear what it is intended, and the specification does not define such.

Claim 2 is indefinite because a kit claim, by definition, must contain two or more elements, and the interrelationships between the elements must be explicitly stated (see In re Venezia, 530 USPQ 2d 956 (CCPA 1975)). In the instant case, it is unclear what is the interrelationship between the agents, i.e., whether they are in a single or separate containers. The claim is further indefinite for the recitation of "its derivative" for the same reason above.

The term "substantially the same" in claim 8 is a relative term which renders the claim indefinite. The term "substantially the same" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term is used to describe an amino acid sequence, and it is unclear, for example, up to what percentage of sequence identity or having what activity, it is still considered "substantially the same".

The remaining claims are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Ames et al., US 2002/0038007.

Ames discloses a human GPCR, 11cb splice variant polypeptide having SEQ ID NO:2, which is a splice variant of SEQ ID NO:11 (SLC-1) of the present invention, as the amino acid sequence of the present SEQ ID NO:11 comprises SEQ ID NO:2 of Ames's with 100% sequence identity (see appended computer printout of sequence search results). The difference between the two sequences is that the present SEQ ID NO:11 comprises additional 69 amino acids at the N-terminus. Ames further teaches that MCH is a ligand for 11cb splice variant (page 19, [0252]). Additionally, Ames teaches a screening method for identifying agonist or antagonist of the 11cb receptor splice variant by binding assays in the presence of *labeled* or unlabeled MCH (page 2, [0023] – [0029], and page 14, [0179]), wherein MCH has SEQ ID NO:7, which is 100% identical to the MCH of SEQ ID NO:2 of the present invention. As such, the reference anticipates the present claims 1, and 8. With respect to the limitation of “the derivative” in claim 9, Ames's *labeled* MCH is a “derivative” of MCH, and “containing” a sequence of the 5th to the 19th amino acids of SEQ ID NO:2, and therefore, meets the limitation, and anticipates the claim.

Claims 1 and 8 are also rejected under 35 U.S.C. 102(e) as being anticipated by Salon et al, US 6,221,616 B1.

Salon discloses a human MCH1 receptor, which is the receptor for MCH (column 41, lines 8-32, and Figures 6 and 7), and has an amino acid sequence (SEQ ID NO:2) 99.8% identical to the SLC-1 (SEQ ID NO:11) of the present invention (see appended computer printout of sequence search results). Salon's MCH1 receptor is a variant of the present SCL-1 as the only difference between the two sequences is a single conservative amino acid substitution. Further, Salon teaches a method of screening chemical compounds to identify a compound specifically binding to the MCH1 receptor by contacting cells or a membrane preparation expressing or containing said MCH1 receptor with a compound such as MCH (column 5, line 45 to column 7, line 2; Figure 7; and claims 1 and 2). Additionally, Salon teaches that mammalian MCH (19 amino acids) is highly conserved between rat, mouse and human, exhibiting 100% amino acid identity (column 1, lines 38-40), indicating the MCH used by Salon is the same as

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that of the present invention, which is the rat MCH. The reference, therefore, anticipates the present claims 1, and 8.

Note: applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ames et al., US 2002/0038007, as applied to claims 1 and 8 above.

The teachings of Ames are reviewed above. Ames does not specifically teach a kit for screening a compound comprising MCH and SLC (as claim 2). However, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to make a kit containing said proteins for the purpose of research and/or clinical applications, such as immunoassays, because such kit would facilitate the applications, and commercial distribution. Further, packing a composition in a kit is old and well known in the art.

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Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Salon et al, US 6,221,616 B1, as applied to claims 1 and 8 above.

The teachings of Salon are reviewed above. Salon does not specifically teach a kit for screening a compound comprising MCH and SLC (as claim 2). However, it would have been obvious over the prior art for the same reasons above.

Note: applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Salon et al, US 6,221,616 B1, as applied to claims 1 and 8 above, and further in view of Maratos-Flier, US 5,849,708.

The teachings of Salon are reviewed above. Salon does not specifically teach a MCH derivative such as those with the N-terminus amino acid deletions in the present invention.

However, Maratos-Flier teaches MCH agonists lacking residues 1-4 of MCH (column 20, lines 51-52), and that the minimal sequence needed to elicit an equipotent response to the native MCH is MCH(5-15), and because fragment analogs lacking residues 1-4 are equipotent to native MCH, they appear to not be required for MCH activity (column 18, lines 40-44, and 50-53).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use a MCH agonist (derivative) taught by Maratos-Flier to identify a compound of altering the binding of MCH to SLC-1 using the method taught by Salon. The person of ordinary skill in the art would have been motivated to make such a labeled peptide for identifying the compound because the identified compound, agonist or antagonist of the receptor, can be used for treating diseases and disorders as indicated by Salon (column 24, line 61 to column 25, line 34), and reasonably would have expected success because Maratos-Flier has demonstrated that such MCH agonists (derivatives) retain the same functional activity.

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Note: applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ames et al., US 2002/0038007, as applied to claims 1, 8, and 2, 9 above, and further in view of Bolton et al. (Biochem. J., 1973, 133:529-539).

The teachings of Ames are reviewed above. Although Ames teaches labeling of MCH in the screening method, Ames does not specify the ^{125}I labeling of the polypeptide or derivatives with a Bolton-Hunter reagent.

Bolton teaches a reagent (Bolton-Hunter reagent) and a method using thereof for labeling of proteins such as hormones to high specific radioactivities by conjugation to a ^{125}I -containing acylating agent, and indicates that the method has the advantages such as introducing ^{125}I into peptides lacking tyrosine (as comparing to the existing methods), and avoids causes of iodination damage of the labeled peptide (page 537, the first paragraph of the left column, and the second paragraph of the right column). Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to label a MCH derivative with ^{125}I with a Bolton-Hunter reagent as taught by Bolton in order to identify a compound of altering the binding of MCH to SLC-1 using the method taught by Ames. The person of ordinary skill in the art would have been motivated to make such a labeled peptide for identifying the compound because the identified compound, agonist or antagonist of the receptor, would have potential therapeutic uses as indicated by Ames (page 16, [0197] – [0200]), and reasonably would have expected success because Bolton has demonstrated the successful labeling of several hormone peptides with the Bolton-Hunter reagent.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maratos-Flier, US 5,849,708, as applied to claim 9 above, and further in view of Bolton et al. (Biochem. J., 1973, 133:529-539).

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Claim 12 is an iodide labeled MCH derivative, MCH(4-19), and it is labeled with Bolton-Hunter reagent.

The teachings of Maratos-Flier, and Bolton are reviewed above. Additionally, Maratos-Flier teaches a method of competitive binding assay for identifying a compound binding to MCH receptor, utilizing radiolabeled MCH, such as iodinating MCH (column 15, lines 35-48).

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to label a MCH derivative with iodide taught by Maratos-Flier with a Bolton-Hunter reagent as taught by Bolton, as the Bolton-Hunter reagent is for labeling a protein such as a hormone with iodide. The person of ordinary skill in the art would have been motivated to make such a labeled peptide as it is useful for identifying compounds as taught by Maratos-Flier, and reasonably would have expected success because Bolton has demonstrated the successful labeling of several hormone peptides with the Bolton-Hunter reagent.

Conclusion:

No claim is allowed.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
7/8/03


LORRAINE SPECTOR
PRIMARY EXAMINER